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COCHRANE REVIEWS

Cochrane Collaborative Review Group on Peripheral Vascular Diseases: Review Abstracts

Introduction

The following abstracts are part of an ongoing series of articles produced by the Cochrane Collaborative Review Group on Peripheral Vascular Diseases, which is part of the Cochrane Collaboration. The reviews are published in full on *The Cochrane Library*, a quarterly electronic journal available on CD-ROM and via the Internet. The electronic format allows Cochrane reviews to accommodate new data as they become available, making the library a consistently up-to-date source of information over time.

The abstracts appearing on the Cochrane Library are now presented in a different, simpler, less scientific format than the abstracts usually presented here to permit greater accessibility to the public. However, the substance of both versions is the same. Review abstracts on Cochrane reviews will be indexed on MedLine in the near future.

If you are interested in writing a Cochrane review or contributing to the activities of the Cochrane Peripheral Vascular Diseases Group please contact:

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Any comments or criticisms on these Cochrane reviews/abstracts should be made through the comments/criticisms facility on the Cochrane Library, or by contacting the group at the above address.

Abstracts

Abstract. Buflomedil for intermittent claudication.
T. L. M. De Backer, R. H. Vander Stichele, and M.G. Bogaert
Date of most recent substantive amendment: 21 February 2000

Background

Intermittent claudication is pain, caused by chronic occlusive arterial disease, that develops in a limb during exercise and is relieved with rest.

Buflomedil is a vasoactive agent claimed to have beneficial effects on the microcirculation. It is used chiefly to treat peripheral vascular disease and to a lesser extent for cerebrovascular arterial disease. However, its clinical efficacy for intermittent claudication has not previously been examined critically.

Objectives

To evaluate the available evidence on the efficacy of buflomedil for intermittent claudication.

Search strategy

Trial reports were sought through Medline, International Pharmaceutical Abstracts (IPA) and the Cochrane Controlled Trials Register. Abbott Laboratories, the distributor of buflomedil, was asked to provide reports of controlled clinical trials. Reference lists of retrieved articles were checked, and enquiries sent to authors of known trials, to identify additional trials.

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Finally, the authors conducted a Science Citation Index search.

Selection criteria

Trial reports had to be double-blinded, randomised, and conformed to our PIO-criteria (Patients, Intervention, Outcome) to be considered for inclusion. Patients were required to have proven intermittent claudication (Fontaine stage II); the intervention was to be oral administration of buflomedil compared to placebo; and outcomes had to include pain-free walking distance (PFWD) and maximum walking distance (MWD) analysed by standardised exercise test.

Data collection and analysis

Searches of bibliographic databases yielded three eligible randomised controlled trials (RCTs) and a meta-analysis referring to nine eligible trials. Two of these nine trials had already been identified; two had been published in journals not referenced in traditional bibliographic indexes; and five were unpublished. Despite multiple requests, details of only one of the five unpublished trials were provided by the author of the meta-analysis, the other four could not be retrieved. Four of the six eligible trials retrieved were subsequently excluded after quality evaluation.

Data on walking distances were extracted from the two remaining trials. Differences in incremental gain between active and placebo groups for PFWD and MWD with their confidence intervals were calculated.

Main results

Both RCTs included in the review showed moderate improvements in PFWD for patients on buflomedil. In one trial this improvement (75 m, 95% CI 37–114) was statistically significant, but in the other, with a wholly diabetic population, it was non-significant (81 m, 95% CI −9–170) compared to placebo. For both RCTs the gains in MWD were statistically significant, but with wide confidence intervals (81 m, 95% CI 30–131; and 171 m, 95% CI 27–316 respectively). Pooling of the data was not attempted.

Reviewers' conclusions

There is little evidence available to evaluate the efficacy of buflomedil for intermittent claudication. Most available trials are of poor quality and were excluded from the review. The two trials included showed moderately positive results but these are undermined by publication bias since we know of another four unpublished, irretrievable, and inconclusive studies.

There is a lack of evidence for the efficacy of buflomedil in intermittent claudication.

Abstract. Home versus in-patient treatment for deep vein thrombosis

I. G. Schraibman, A. A. Milne, and E. M. Royle

Date of most recent substantive amendment: 6 February 2001

Background

Deep vein thrombosis (DVT) affects 1–2/1,000 of the adult population per annum in western societies. It may be associated with pulmonary embolism (PE) which carries a 10% fatality rate. Sufferers may develop post-thrombotic syndrome with swelling of the leg, secondary varicose veins and ulceration. In the initial stages of treatment for DVT, patients are traditionally admitted to hospital for intravenous treatment with unfractionated heparin (UH) for three to five days. The dose of UH required to provide a therapeutic level of anticoagulation is unpredictable, so the blood must be closely monitored. Fractionated, or low molecular weight heparin (LMWH), is given subcutaneously once daily and requires no monitoring, so can be given in hospital or at home.

Objectives

To collate all randomised controlled trials (RCTs) comparing a home treatment regime (LMWH) with hospital treatment (LMWH or UH) for the initial phase of treatment for DVT, and to compare the safety, efficacy, patient acceptability and cost implications of home versus in-patient treatment.

Search strategy

All published reports of home treatment were traced through MEDLINE, and EMBASE (up to and including

December 2000) using the search strategy described by the Cochrane Peripheral Vascular Diseases Group. Additional searches included the Cochrane CCTR/CENTRAL database, handsearching non-listed journals, and personal communication with researchers.

Selection criteria

RCTs of home versus hospital treatment for DVT in which DVT was clinically confirmed and treated with either LMWH or UH.

Data collection and analysis

One reviewer selected the material for inclusion (IGS): another (AAM) reviewed the literature and selection of trials, and the third (EMR) cross-checked the data. Outcomes included PE, recurrent DVT, gangrene, heparin complications, and death.

Main results

Only two major RCTs with comparable treatment arms were found. Both had fundamental problems, including high exclusion rates, partial hospital treatment of many in the LMWH arms, and comparison of UH in hospital with LMWH at home. The trials showed that home treatment was no more liable to complications than hospital treatment. Initial results from a smaller RCT comparing LMWH treatment in both home and hospital arms came to the same conclusion.

Reviewers' conclusions

The limited evidence suggests that home management is cost effective, and likely to be preferred by patients. Further large trials comparing these treatments are unlikely to be held. Therefore, home treatment is likely to become the norm, and further research will be directed to resolving practical issues.